REMARKS

Generally

Claims 12-13 are pending in the application. The specification remains objected to because of a blank government contract number. A further objection has been raised with regard to acknowledgement of a registered trademark.

Claims 12-13 are newly rejected under 35 USC §112, 1st paragraph for not disclosing "output to memory." Claims 12-13 are newly rejected under 35 USC §112, 2nd paragraph on antecedent basis issues. Claims 12-13 remain rejected under 35 USC §101 as directed to non-statutory subject matter.

Claims 12-13 stand newly rejected under 35 USC §103(a) as being unpatentable over: Lai *et al.* (Biochimica et Biophysica Acta, Vol. 1517, Pages 449-454, 2001) - hereinafter "LAI," in view of Bensen *et al.* (Nucleic Acids Research, Vol. 21, Pages 2963-2965, 1993) - hereinafter "BENSEN," and in further view of U.S. Patent No. 7,142,989 to Aoki *et al.*, hereinafter "AOKI."

This Reply acknowledges the need for a government contract number should an investigation reveal that the claimed invention was first conceived or reduced to practice in the performance of work under a government contract containing, or required to contain, a clause to that effect. This Reply distinguishes the use of "UNIGENE" from its use as a registered trademark.

The claims have been amended to address the rejections under §112 (both 1st and 2nd paragraphs) and §101.

The claims have been amended, and one new claim added, to distinguish the claims from LAI, BENSEN, and AOKI.

Regarding the Specification

The OA asserts that the registered trademark "UNIGENE" should be capitalized wherever it appears and be accompanied by generic terminology. "UNIGENE" as a registered mark refers to genetic engineering and biochemistry research and consulting services offered by Unigene Laboratories, Inc. However, as used in the specification, "Unigene" also refers to the NCBI database of the transcriptome, and is not a registered trademark.

The OA asserts objects to the specification on the grounds that information, a contract number, relating to federally sponsored research and development is missing. The OA states that until such reference is added, the objection shall be maintained. The undersigned appreciates the Office's position. Our investigation into whether the claimed invention was conceived or first actually reduced to practice in the performance of work under a government contract (the criteria for requiring such a statement) is ongoing. Should the investigation result in the conclusion that the claimed invention was not conceived of first reduced to practice in the performance of work under a government contract, the paragraph will be deleted.

Regarding Rejection Under 35 USC §112 1st Paragraph

The OA asserts at P04 with regard to Claims 12-13:

`The specification does not disclose` <the exact claim language>.

The Board of Patent Appeals and Interferences has stated that the Office "has the initial burden of presenting evidence or reasons why persons skilled in the art would not recognize in [the] specification disclosure a description of the invention defined by the claims."[1] The Court of Appeals for the Federal Circuit (CAFC) has commented that the fact that "the exact words … are not in the specification is not important."[2]

[1] *Ex parte* Sorenson, 3 USPQ2d 1462, 1463 (BPAI 1987).
[2] *In re* Wright, 866 F.2d 422, 9 USPQ2d 1649 (Fed. Cir. 1989).

While the undersigned appreciates the Examiner's position and directs the Examiner's attention to the following portions of the specification for support for the amended claim language, the OA fails to state a *prima facie* case for rejection under §112 1st paragraph because the original specification contains substantial disclosure, e.g., [0100], that would lead persons skilled in the art to recognize storage in memory of the identity of inferred sequences. The undersigned apologizes for indicating [0009] as providing such disclosure - [0010] was intended.

As further indication that a person skilled in the art would recognize storage in memory (or display) as disclosed in the specification, the following portions of the specification are offered (**bold emphasis** added).

> *[0060] In some embodiments of the present invention, the process of ...* ***parsing the results to identify candidate genomic sequences is implemented as a computer program product****. Computer program products of this invention include the ability to ...* ***output unique sequences*** *for evaluation for oligonucleotides amenable to hybridization. Intermediate and final* ***results can be made available for user inspection****. ….* ***Operator interface to such computer program products is preferably provided through graphical user interface (GUI)*** *technologies known to those skilled in the art.*
>
> *[0065] At this point, the certain oligonucleotides can be identified as unique ... These* ***oligonucleotides … can be saved to a database*** *...*

It is beyond question that persons skilled in the art would recognize "output to memory" of inferred sequences as claimed.

Regardless, the claims have been amended to include the limitation "output to the user for inspection" as supported at least in part by [0060].

Regarding Rejection Under 35 USC §112 2nd Paragraph

The OA rejects the for lacking antecedent basis for "the results" in Claims 12-13 and for "the computer program product" in Claim 13. Both claims have been amended to address these rejections.

Regarding Rejection Under 35 USC §101

The OA asserts that Claims 12-13 are rejected under 35 USC §101 because the claimed invention is directed to non-statutory subject matter and failing to either, i) transform an article or physical object to a different state or thing, or ii) otherwise produce a useful, concrete, and tangible result.

The OA fails to state a *prima facie* rejection under 35 USC §101 against Claim 13. Claim 13 is directed to a computer program product[3] embodied in a computer readable medium. The computer readable medium is an "article" and a "physical object" having a state that is transformed by the operation of various modules stored thereon. The OA summarily asserts no physical transformation and provides no rationale related to the limitations of Claim 13. **Nonetheless, Claim 13 has been amended to recite a "physical" medium so as to distinguish such medium from a signal. Original disclosure, e.g., found in paragraphs [0060] *et seq*., support this limitation.**

The OA asserts that Claim 12 does not produce a tangible result, but states that the rejection could be overcome by reciting that a specific final result of the process is output to a user. As noted above, [0060] supports such a limitation. That limitation has been added to Claim 12.

[3] The word "product" was left out in the preamble of the initial presentation of Claim 13. However, the first element of the claim body recites "a computer readable medium" with support from at least [0060].

Regarding Rejection Under 35 USC §103

Claims 12 and 13 have been amended to more particularly point out the claimed invention by the addition of the following limitations.

> *parsing results of the search for those sequences having homology above a threshold with at least one set of organisms other than the set under investigation and otherwise unique within the selected genomic database,*
>
> *outputting to a user an identity of those sequences having homology above a threshold with at least one set of organisms other than the set under investigation and otherwise unique within the selected genomic database.*

Neither LAI, nor BENSON, nor AOKI disclose methods/computer program products for finding **unique** genomic sequences. Original disclosure, e.g., at [0500], describes "unique" and "uniqueness" as for the purpose of the application.

CONCLUSION

The foregoing is submitted as a full and complete response to the OA mailed 02/04/2008. With consideration of the above remarks directed to the rejections, the undersigned submits that this application is in condition for allowance, and such disposition is earnestly solicited.

The OA contains characterizations of the claims and the references with which the Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the OA.

In discussing the specification, claims, and drawings in this Reply, it is to be understood that Applicants are in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification and/or shown in the drawings. Rather, Applicants are entitled to have the claims interpreted to the maximum extent permitted by statute, regulation, and applicable case law.

The undersigned believe that the prosecution might be advanced by discussing the application with the Examiner. The undersigned requests an interview with the Examiner at the Examiner's earliest convenience.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 50-1458, and please credit any excess fees to such deposit account.

Respectfully submitted,

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